DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Brian E. Harvey, M.D., Ph.D.
Vice President, U.S. Regulatory Strategy
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

RE: NDA # 050797
Zmax® (azithromycin extended release) for oral suspension
MA #175

Dear Dr. Harvey:

As part of its routine monitoring and surveillance program, the Office of Prescription Drug Promotion (OPDP), Division of Consumer Drug Promotion (DCDP) of the U.S. Food and Drug Administration (FDA) has reviewed a "1 Day. 1 Dose" Brochure (ZMU00162APDF/282549-01) (brochure) for Zmax® (azithromycin extended release) for oral suspension (Zmax) submitted by Pfizer Inc. (Pfizer) under cover of Form FDA-2253. The brochure is false or misleading because it omits and minimizes important risk information, makes unsubstantiated superiority claims, omits material facts, broadens the indication for the drug product, makes misleading efficacy claims, and makes unsubstantiated claims for Zmax. Therefore, the brochure misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 352(a); 321(n). *Cf.* 21 CFR 202.1(e)(5)(i) & (iii); (e)(6)(i) & (ii); (e)(7)(i) & (viii).

Background

Below are the indication (in pertinent part), and summary of the most serious and most common risks associated with the use of Zmax.[1,2]

Zmax is indicated for the treatment of mild to moderate infections caused by susceptible isolates of the designated microorganisms in the specific conditions listed below:

- **Acute bacterial sinusitis** in adults due to *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*.

[1] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.
[2] The version of the approved product labeling for Zmax (PI) that was approved when the piece cited in this letter was disseminated and the version referred to in this letter is dated 06/2009. However the most recent version of the PI, which includes additional risks and contraindications, was approved on 03/01/2012.

- **Community-acquired pneumonia** in adults and pediatric patients six months of age or older due to *Chlamydophila pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae,* in patients appropriate for oral therapy. Pediatric use in this indication is based on extrapolation of adult efficacy.

Zmax is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide or ketolide antibiotic. The FDA-approved product labeling (PI) for Zmax includes Warnings and Precautions for severe (including fatal) allergic and skin reactions, *Clostridium difficile*-associated diarrhea, exacerbation of myasthenia gravis, gastrointestinal disturbances, prolongation of QT interval, and development of drug resistant bacteria. The most common adverse reactions associated with Zmax include diarrhea/loose stools, nausea, abdominal pain, headache, and vomiting.

Omission and Minimization of Risk Information

Promotional materials are misleading if they fail to reveal material facts in light of representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. Although the brochure contains information regarding the most commonly reported adverse events, it fails to include information regarding a serious warning and precaution associated with the use of Zmax. Specifically, the brochure omits the important risk of QT prolongation associated with Zmax use. The WARNINGS AND PRECAUTIONS section of the PI states, "[p]rolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and *torsades de pointes*, have been seen in treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization" (emphasis in original). By omitting this serious risk associated with Zmax, the brochure misleadingly suggests that the drug is safer than has been demonstrated.

In addition, the brochure minimizes the risks associated with Zmax by failing to disclose that severe and fatal allergic and skin reactions have been observed with azithromycin. Specifically, the WARNINGS AND PRECAUTIONS section of the PI states (emphasis in original):

> "Serious allergic reactions, including angioedema, anaphylaxis, Stevens Johnson syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy using other formulations. Although rare, fatalities have been reported. Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms **recurred soon thereafter in some patients without further azithromycin exposure**."

We acknowledge that page seven of the brochure states, "Seek emergency help right away if you develop hives, skin rash, sores in your mouth, trouble swallowing, swelling of your face, tongue, or throat or have wheezing or trouble breathing after Zmax"; however, failure to disclose the severity of the potentially fatal allergic reactions, including recurrence of the allergic symptoms even when the drug was discontinued, that have been observed with azithromycin misleadingly minimizes the risks associated with Zmax.

Promotional materials are misleading if they fail to present information about risks associated with a drug with a prominence and readability reasonably comparable with the presentation of information related to the effectiveness of the drug. The brochure prominently presents efficacy claims in large bolded font size and in colorful text and graphics surrounded by a significant amount of white space; in contrast, the risk information is placed in obscure locations, in block paragraph format, without the use of headers or other signals to alert readers to its significance. The overall effect of this presentation undermines the communication of important risk information, minimizing the risks associated with Zmax, and misleadingly suggests that Zmax is safer than has been demonstrated. We note that the statement "*Please see Zmax full Patient and Prescribing Information, attached*" (emphasis original) is included in the brochure. However, this does not mitigate the misleading risk presentation.

Unsubstantiated Safety Superiority Claim/Minimization of Risk Information

Promotional materials are misleading if they contain representations or suggestions that a drug is safer or more effective than another drug, when this has not been demonstrated by substantial evidence or substantial clinical experience. The brochure includes the following claims (emphasis original):

- **"Will my child be able to handle a medicine with just one strong dose?**

  Zmax is different from other drugs, because it's not released in the stomach. *Zmax* goes to work in the small intestine so it's easier on the stomach. Unlike many other drugs, you should take Zmax on an empty stomach."

The above claims are misleading because they imply that Zmax demonstrates a superior safety profile when compared to other antibiotics, due to the supposed superior tolerability of the drug. FDA is not aware of adequate and well-controlled head-to-head studies to support this implication. Furthermore, the suggestion that pediatric patients will necessarily tolerate Zmax minimizes the risk of gastrointestinal adverse events that may occur while using this drug product. The ADVERSE REACTIONS section of the PI states, "[t]he most common treatment-related adverse reactions in pediatric subjects were gastrointestinal in nature." Moreover, the PI states that vomiting, diarrhea, loose stools, and abdominal pain were the most common adverse events reported in the pediatric studies; therefore, claims that minimize the gastrointestinal adverse events associated with Zmax are misleading. The above claims are particularly concerning considering that the PI for Zmax includes a Warning and Precaution regarding gastrointestinal disturbances.

Omission of Material Facts

Promotional materials are false or misleading if they fail to reveal facts that are material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the materials. The brochure omits important information regarding the dosage and administration of Zmax. Specifically, the brochure fails to include information regarding the required course of action in the event that a patient vomits after administration of the drug. The PATIENT COUNSELING INFORMATION section of the PI states, "Patients who vomit within the first hour should contact their health care provider about further treatment." Additionally, the DOSAGE AND ADMINISTRATION section of the PI states that ". . . if a patient vomits between 5 and 60 minutes following administration, alternative therapy should be considered." The omission of this important information, coupled with claims such as "1 dose and you're done" diminishes the significance of the consequences that may result from the use of Zmax as recommended in the brochure, and is therefore misleading.

The brochure also includes the following claims (emphasis in original):

- **"Will a 1-day, 1-dose antibiotic work?**

  In clinical trials, *Zmax* worked just as well as other antibiotics that needed to be dosed for 7 days."

The above presentation misleadingly suggests that Zmax demonstrates similar efficacy when compared to a wide array of antibiotics when this is not supported by substantial evidence or substantial clinical experience. According to the CLINICAL STUDIES section of the PI, the pivotal studies for Zmax included comparator arms where patients received either clarithromycin or levofloxacin. Failure to disclose this information, coupled with the claim that Zmax "worked just as well as other antibiotics," implies that Zmax demonstrates similar efficacy compared to an extensive group of antibiotics, when this is not the case, and is therefore misleading.

Broadening of Indication

Promotional materials are misleading if they suggest that a drug is useful in a broader range of patients or conditions than has been demonstrated by substantial evidence or substantial clinical experience. The brochure includes the following claim (bolded emphasis in original, underlined emphasis added):

- **"Zmax fights bacteria that cause certain infections, <u>including</u> bacterial sinusitis in adults, and pneumonia in adults and children 6 months and older."**

The above presentation of the indication for Zmax is misleading because it implies that Zmax is indicated to treat additional types of infections, other than acute bacterial sinusitis and community-acquired pneumonia, when this is not the case. Specifically, the use of the word "including," following the words "certain infections," implies that Zmax is used to treat infections **in addition** to those for which the drug is indicated to treat. According to the PI, Zmax is approved to treat "mild to moderate infections caused by susceptible isolates of the

designated microorganisms" in the following **specific** conditions: acute bacterial sinusitis in adults, and community-acquired pneumonia in adults and pediatric patients six months of age and older. Therefore, any suggestion that Zmax may be used to treat conditions other than, or in addition to, those for which Zmax has been FDA-approved is misleading.

The brochure also includes the following presentation: (emphasis original)

> "**Do you or your child have any of these symptoms?**
> - Fever
> - Cough
> - Chills
> - Chest pain
> - Low in energy
> - Tired
>
> If so, talk to your doctor, as it may be germs in the body that need to be treated with an antibiotic."

The totality of this presentation misleadingly suggests that Zmax is approved to treat any conditions associated with the listed symptoms, including viral infections that cause influenza or the common cold, when this has not been demonstrated by substantial evidence or substantial clinical experience. The FDA-approved patient labeling (PPI) states, "Zmax only works against bacteria. It does not work against viruses, like the common cold or flu." Thus, failure to disclose this material information misleadingly broadens the indication for Zmax.

Unsubstantiated Superiority Claims

Promotional materials are misleading if they represent or suggest that a drug is safer or more effective than another drug, when this has not been demonstrated by substantial evidence or substantial clinical experience. The brochure includes the following claims: (emphasis original)

- "**What are the benefits of an antibiotic that is given as a 1 day, 1 dose?**

  For Adults: . . .

  - Your body gets more medicine on Day 1 when it needs it most"

The totality of these claims misleadingly suggests that Zmax is clinically superior to other antibiotics because of its "1 day, 1 dose" dosage regimen. However, the clinical studies for Zmax only demonstrated that Zmax was **non-inferior** to a ten day dosage regimen of levofloxacin for the treatment of acute bacterial sinusitis and a seven day dosage regimen of both levofloxacin and clarithromycin for the treatment of community acquired pneumonia. In general, claims of superiority must be supported by adequate and well-controlled head-to-head clinical trials comparing appropriate doses and dose regimens of your drug and the comparator drug or drugs. FDA is not aware of any substantial evidence or substantial clinical experience that supports the implication that Zmax is clinically superior to other antibiotic treatments due to its dosage regimen. If you have data to support these claims,

please submit them to FDA for review.

Misleading Efficacy Claims

The brochure includes the following presentations (bolded emphasis in original; underlined emphasis added):

- "**1 DAY. 1 DOSE.**

  And your treatment is done.*

  . . . *Dosing of treatment is complete; however, *Zmax* will continue to work in your system for <u>10 days</u>."
- "**Is 1 dose enough?**

  With just 1 dose, the medicine in *Zmax* goes on to work in you or your child for <u>10 days</u>."
- "**1 dose and you're done, but *Zmax* keeps on working for <u>10 days</u>**," accompanied by an image of an arrow with a highlighted panel which fades progressively from day 1 to day 10.

These presentations misleadingly suggest that Zmax demonstrates clinically significant efficacy for a period of time (i.e., for 10 days following administration) not demonstrated in the clinical trials that evaluated Zmax for the treatment of acute bacterial sinusitis and community-acquired pneumonia. We acknowledge that in the clinical trials for Zmax, clinical and microbiologic evaluations for both approved indications were conducted at the Test of Cure visit, 7 to 14 days post treatment. However, since Zmax is only administered one time as a single dose, it is unclear exactly how long the extent of the therapeutic benefit would be maintained. Therefore, any suggestion that the clinical effect of Zmax for the treatment of acute bacterial sinusitis and community-acquired pneumonia lasts for 10 days following administration is misleading. FDA is not aware of any substantial evidence or substantial clinical experience supporting any claim that Zmax demonstrates clinical efficacy for the treatment of either acute bacterial sinusitis or community-acquired pneumonia for 10 days following administration. If you have data to support these claims, please submit them to FDA for review.

Unsubstantiated Claims

The brochure includes the following claims (emphasis in original):

- "**84% of adult patients said they would most likely take *Zmax* again for the same infection**"
- "**78% of parents said they would most likely use *Zmax* to treat their kids again**"

These claims misleadingly suggest that adult patients and parents of pediatric patients (caretakers) would take Zmax again if they were to have the same infection, when these outcomes are not supported by substantial evidence or substantial clinical experience. Specifically, the support for these claims is based on patient and caretaker responses to the

following telephone survey questions approximately 5-10 days after taking Zmax: “Would you take Zmax again?” and “How likely are you to give your child Zmax again?,” respectively. The use of responses to these survey questions is not sufficient to support the outcomes claimed because these survey questions cannot adequately assess all of the various factors (e.g., all aspects of efficacy, adverse events, and cost) which may influence patients’ or caretakers’ decisions to take any particular treatment again. If you have substantial evidence or substantial clinical evidence to support these claims, please submit them to FDA for review.

Additionally, the brochure includes the following claim (emphasis in original):

- “**80% also agreed *Zmax* made it much easier to complete treatment as directed by their physician**”

This claim misleadingly suggests that treatment with Zmax is “much easier” to complete as compared to other antibiotic products, when this is not supported by substantial evidence or substantial clinical experience. Specifically, in support of this claim, the brochure references patient responses to the following survey question: “Was Zmax easier or harder to take than other medicines?” The use of responses to this single question is not sufficient to support the outcomes claimed because it does not assess whether the effects of the drug, combined with its risks, translate into an overall “easier” treatment to complete as compared to other antibiotic treatment options. As described in the Background section above, Zmax is associated with numerous risks, including several warnings and precautions, and common adverse reactions, which are all factors that may negatively impact a patient’s perception of the “eas[e]” of completing treatment with a given drug therapy. If you have substantial evidence or substantial clinical evidence to support this claim, please submit them to FDA for review.

Conclusion and Requested Action

The brochure is false or misleading because it omits and minimizes important risk information, makes unsubstantiated superiority claims, omits material facts, broadens the indication for the drug product, makes misleading efficacy claims, and makes unsubstantiated claims for Zmax. Therefore, the brochure misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 352(a); 321(n). *Cf.* 21 CFR 202.1(e)(5)(i) & (iii); (e)(6)(i) & (ii); (e)(7)(i) & (viii).

OPDP requests that Pfizer immediately cease the dissemination of violative promotional materials for Zmax such as those described above. Please submit a written response to this letter on or before July 3, 2012, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Zmax that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials. Please direct your response to the undersigned by facsimile at (301) 847-8444, or at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, Division of Consumer Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. Please note that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has been

reorganized and elevated to the Office of Prescription Drug Promotion (OPDP). OPDP consists of the Immediate Office, the Division of Professional Drug Promotion (DPDP) and DCDP. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. In addition, OPDP recently migrated to a different tracking system. Therefore, OPDP letters will now refer to MA numbers instead of MACMIS numbers. Please refer to the MA # in addition to the NDA number in all future correspondence relating to this particular matter. DCDP/OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Zmax comply with each applicable requirement of the FD&C Act.

Sincerely,

{See appended electronic signature page}

Adora Ndu, Pharm.D.
LCDR, USPHS
Regulatory Review Officer
Division of Consumer Drug Promotion
Office of Prescription Drug Promotion

Amy Toscano, Pharm.D., CPA
Team Leader
Division of Consumer Drug Promotion
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ADORA NDU
06/19/2012

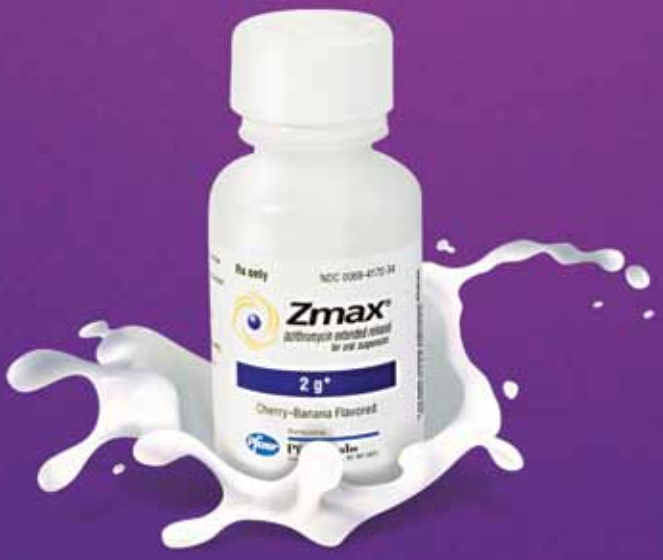
AMY TOSCANO
06/19/2012

From the makers of Z-Pak® (azithromycin) 250 mg

Did you hear about the antibiotic *Zmax*?

1 DAY. 1 DOSE.

And your treatment is done.*



Zmax fights bacteria that cause certain infections, including bacterial sinusitis in adults, and pneumonia in adults and children 6 months and older. Like other antibiotics, Zmax takes time to work.

Please see Zmax full Patient and Prescribing Information, attached.

*Dosing of treatment is complete; however, *Zmax* will continue to work in your system for 10 days.

Single Dose

Zmax®
(azithromycin extended release)
for oral suspension

www.ZmaxInfo.com

Zmax
FOR NO MORE THAN $20

Bring this coupon and your prescription for *Zmax* to your pharmacist to cut your cost and pay no more than $20.*

- **To the pharmacist for a patient paying with cash:** Please submit this claim to **Therapy First Plus**. A valid Other Coverage Code is required. The patient's maximum amount to pay will be no more than $20.00 or their co-pay, whichever is less. You will receive the remaining balance in your next reimbursement from **Therapy First Plus,** and a handling fee.

- **To the pharmacist for a patient with an authorized third-party payor:** Submit the claim to the Primary Third-Party Payor. Then, submit the balance due to **Therapy First Plus** as a Secondary Payor as a co-pay–only billing, using Other Coverage Code indication. The patient's maximum amount to pay will be $20.00 or their co-pay, whichever is less. You will receive the remaining balance in your next reimbursement from **Therapy First Plus,** and a handling fee.

- **Submit this claim/information to Therapy First Plus:**

  Bin Number: 004682
  Group ID: LCPAW447
  RxPCN: CN
  Cardholder ID: PAW007889684

This offer is not health insurance.
***Please see eligibility criteria on back**

Zmax® (azithromycin extended release) for oral suspension

For any questions regarding **Therapy First Plus** online processing, please call the Help Desk at 1-800-422-5604. I certify that my participation in this program is in compliance with all applicable state laws and any obligations, contractual or otherwise, that I have as a pharmacy provider. I also agree to retain the coupon for 3 years or as otherwise required by law, whichever is longer, and grant Pfizer Inc the right to audit any of my submissions. By using this coupon, I am confirming that I have met the eligibility criteria and agree to the terms and conditions of this program.

Eligibility Criteria: 1. This coupon is not valid for prescriptions purchased under Medicaid, Medicare, (including Medicare Part D), or other federal or state programs including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"], or by private indemnity or HMO insurance plans or other health or pharmacy programs which reimburse you for the entire cost of your prescription drugs. **2.** Coupon is limited to $20 or the amount of your co-pay, whichever is less. **3.** You must deduct the value of this coupon from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf. **4.** This coupon is not valid for residents of Massachusetts whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law. Coupon cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. **5.** Offer good only in the US and Puerto Rico. **6.** Pfizer Inc reserves the right to rescind, revoke, or amend this offer without notice. You understand and agree to comply with the terms and conditions of this offer. Not available through mail order.

This coupon will be accepted only at participating pharmacies. Offer good only in US and Puerto Rico. I agree to the terms and conditions received with this coupon. No membership fees.

For any questions, call Customer Service at 1-877-465-6437. www.Pfizer.com

Pfizer Inc, 235 East 42nd Street, New York, NY 10017

This offer expires 12/31/11.

10% TOTAL RECOVERED FIBER

Pfizer

Zmax® (azithromycin extended release) for oral suspension

Zmax:
1 DAY. 1 DOSE. And your treatment is done

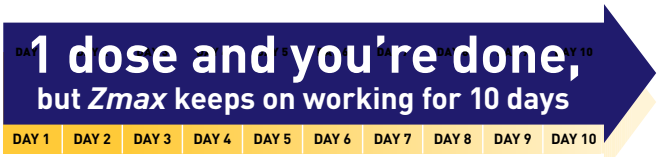
Do you or your child have any of these symptoms?

- Fever
- Cough
- Chills
- Chest pain
- Low in energy
- Tired

If so, talk to your doctor, as it may be germs in the body that need to be treated with an antibiotic.

Is 1 dose enough?

With just 1 dose, the medicine in *Zmax* goes on to work in you or your child for 10 days.



Do not take Zmax if you are allergic to anything in Zmax or antibiotics like erythromycin or telithromycin.

Please see Zmax full Patient and Prescribing Information, attached.

Will a 1-day, 1-dose antibiotic work?

In clinical trials, *Zmax* worked just as well as other antibiotics that needed to be dosed for 7 days. In fact, 9 out of 10 patients treated for community-acquired pneumonia were cured.

What are the benefits of an antibiotic that is given as a 1 day, 1 dose?

For Adults: If you are sick, a 1-dose option makes treatment easier on you.

- Your body gets more medicine on Day 1 when it needs it most
- No need to worry about missing a dose

For Children: It can be tough to give your child medicine but treating with *Zmax* means:

- 1 dose and your child is done with treatment
- No need to keep track of multiple day doses

The most common side effects in adults are diarrhea/loose stools, nausea, stomach pain, headache, and vomiting.

The most common side effects in children are vomiting, diarrhea/loose stools, nausea, and stomach pain.

Single Dose
Zmax®
(azithromycin extended release)
for oral suspension

1 Day. 1 Dose.

www.ZmaxInfo.com

Zmax:
1 DAY. 1 DOSE. And your treatment is done

If the whole therapy is just 1 dose, will I or my child get better faster?

Like all antibiotics, *Zmax* does take time to work. Most kids begin to feel good in just 2 to 3 days. If symptoms are not better by Day 4, call your doctor.

Will my child be able to handle a medicine with just one strong dose?

Zmax is different from other drugs, because it's not released in the stomach. *Zmax* goes to work in the small intestine so it's easier on the stomach. Unlike many other drugs, you should take *Zmax* on an empty stomach.

My child always complains about the taste of medicine.

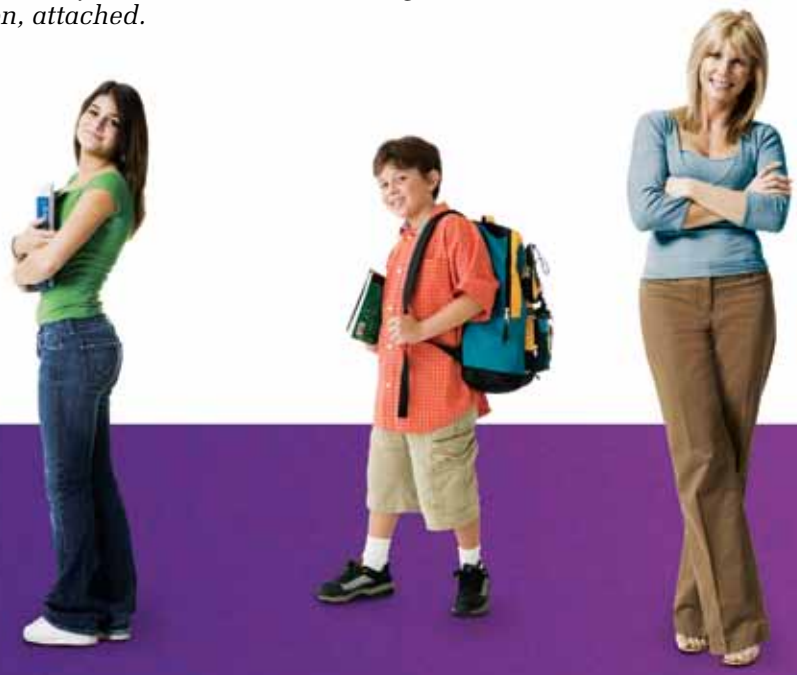
Zmax is in an easy to swallow liquid, with a cherry-banana flavor.

Please see Zmax full Patient and Prescribing Information, attached.

Do not take Zmax if you are allergic to anything in Zmax or antibiotics like erythromycin or telithromycin.

Seek emergency help right away if you develop hives, skin rash, sores in your mouth, trouble swallowing, swelling of your face, tongue, or throat, or have wheezing or trouble breathing after taking Zmax.

Call your doctor right away if you have diarrhea that does not go away, is severe, watery, or has blood in it. Diarrhea can occur as late as two or more months after you take an antibiotic such as Zmax. This can be a sign of a serious illness.



Single Dose Zmax® (azithromycin extended release) for oral suspension

1 Day. 1 Dose.

www.ZmaxInfo.com

What people are saying about *Zmax**...

- **84% of adult patients said they would most likely take *Zmax* again for the same infection**
- **80% also agreed *Zmax* made it much easier to complete treatment as directed by their physician**
- **78% of parents said they would most likely use *Zmax* to treat their kids again**

Ask your doctor today about *Zmax*, the 1-day, 1-dose antibiotic.

In patients with myasthenia gravis taking macrolides, including Zmax, there have been reports of beginning or worsening of a nerve-muscle condition called myasthenia gravis. Its symptoms include muscle weakness, eye lid drop, and difficulty breathing.

*According to a survey of 502 patients conducted by Triple i and sponsored by Pfizer Inc, 2009. Data on file. Pfizer Inc, New York, NY.

Single Dose

Zmax®
(azithromycin extended release)
for oral suspension

www.ZmaxInfo.com

10% TOTAL RECOVERED FIBER

Pfizer

Zmax
FOR NO MORE THAN $20

Bring this coupon and your prescription for *Zmax* to your pharmacist to cut your cost and pay no more than $20.*

- **To the pharmacist for a patient paying with cash:** Please submit this claim to **Therapy First Plus**. A valid Other Coverage Code is required. The patient's maximum amount to pay will be no more than $20.00 or their co-pay, whichever is less. You will receive the remaining balance in your next reimbursement from **Therapy First Plus,** and a handling fee.

- **To the pharmacist for a patient with an authorized third-party payor:** Submit the claim to the Primary Third-Party Payor. Then, submit the balance due to **Therapy First Plus** as a Secondary Payor as a co-pay–only billing, using Other Coverage Code indication. The patient's maximum amount to pay will be $20.00 or their co-pay, whichever is less. You will receive the remaining balance in your next reimbursement from **Therapy First Plus,** and a handling fee.

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  Group ID: LCPAW447
  RxPCN: CN
  Cardholder ID: PAW007889684

This offer is not health insurance.
***Please see eligibility criteria on back**

Zmax® (azithromycin extended release) for oral suspension

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Eligibility Criteria: 1. This coupon is not valid for prescriptions purchased under Medicaid, Medicare, (including Medicare Part D), or other federal or state programs including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico [formerly known as "La Reforma de Salud"], or by private indemnity or HMO insurance plans or other health or pharmacy programs which reimburse you for the entire cost of your prescription drugs. **2.** Coupon is limited to $20 or the amount of your co-pay, whichever is less. **3.** You must deduct the value of this coupon from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf. **4.** This coupon is not valid for residents of Massachusetts whose prescriptions are covered in whole or in part by third-party insurance, or where otherwise prohibited by law. Coupon cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. **5.** Offer good only in the US and Puerto Rico. **6.** Pfizer Inc reserves the right to rescind, revoke, or amend this offer without notice. You understand and agree to comply with the terms and conditions of this offer. Not available through mail order.

This coupon will be accepted only at participating pharmacies. Offer good only in US and Puerto Rico. I agree to the terms and conditions received with this coupon. No membership fees.

For any questions, call Customer Service at 1-877-465-6437. www.Pfizer.com

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Pfizer

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Zmax for no more than $20

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- **Submit this claim/information to Therapy First Plus:**

  Bin Number: 004682
  Group ID: LCPWC345
  RxPCN: CN
  Cardholder ID: PWC537151552

This offer is not health insurance.
***Please see eligibility criteria on back.**

Zmax®
(azithromycin extended release)
for oral suspension

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